

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF OREGON

BETTY PHELPS and
DELBERT PHELPS,

Civ. No. 6:09-cv-06168-TC
OPINION AND ORDER

Plaintiffs,

v.

WYETH, INC.; SCHWARZ
PHARMA, INC.; PLIVA USA, INC.;
NORTHSTAR RX LLC; and ALAVEN
PHARMACEUTICAL

Defendants.

Aiken, Chief Judge:

Plaintiffs bring this action alleging that Betty Phelps was injured after ingesting generic metoclopramide produced by defendants Pliva USA, Inc. (Pliva) and Northstar Rx LLC (Northstar) (“generic defendants”). Plaintiffs also allege that Wyeth, Inc. (Wyeth), Schwarz Pharma, Inc.

(Schwarz), and Alaven Pharmaceutical (Alaven), manufacturers of the name-brand version of metoclopramide (“name-brand defendants”), are liable for their injuries.

In June 2010, the court granted summary judgment in favor of the name-brand defendants Wyeth, Schwarz, and Alaven and dismissed all claims against them. On September 19, 2011, plaintiffs filed a motion for a relief from that ruling, which the name-brand defendants opposed. Following the Supreme Court’s ruling in *Pliva, Inc. et al. v. Mensing*, 131 S. Ct. 2567 (2011), the parties filed supplemental motions. Northstar filed a motion for summary judgment, Pliva filed a motion to dismiss, and plaintiffs filed a motion for partial summary judgment. Following oral arguments on September 15, 2011, plaintiffs were given leave to file a motion to file an amended complaint. On November 22, 2011, Judge Coffin granted plaintiffs’ motion to file an amended complaint, and plaintiffs filed their first amended complaint adding a claim against Pliva for failure to update its generic warning label to match the name-brand counterpart’s label.

On November 23, 2011, Magistrate Judge Coffin recommended that the court deny plaintiffs’ motion for a relief from judgment. Judge Coffin also recommended that the court grant Northstar’s motion for summary judgment and Pliva’s motion to dismiss based on federal preemption. Further, Judge Coffin recommended that the court deny plaintiffs’ motion for partial summary judgment. Plaintiffs timely filed objections to Judge Coffin’s findings. Additionally, defendant Pliva objects to plaintiffs’ amended claims as preempted and argue that the issue is not properly before the court at this time.

Subsequently, plaintiffs filed a motion requesting sanctions for Pliva’s failure to produce copies of the labeling that accompanied its metoclopramide products between 2003 and 2008 during discovery. Plaintiffs argue that Pliva’s failure to disclose the fact that its label differed from the

name-brand's label deprived both plaintiffs and the court of necessary information. Consequently, plaintiffs assert that sanctions are required under Federal Rule of Civil Procedure 26 and should be awarded under Federal Rule of Civil Procedure 37. Judge Coffin issued a second Findings and Recommendations and declined to impose sanctions, and plaintiffs object.

When a party objects to a magistrate judge's findings and recommendations regarding a dispositive issue, the district court must make a *de novo* determination of that portion of the magistrate judge's report. Fed. R. Civ. P. 72(b)(3); *see* 28 U.S.C. § 636(b)(1)(c); *McDonnell Douglas Corp. v. Commodore Business Machines, Inc.*, 656 F. 2d 1309, 1313 (9th Cir. 1981). For non-dispositive motions, the magistrate's findings are reviewed for clear error. Fed. R. Civ. Pro. 72(a); *Henry v. Gill Indust., Inc.*, 983 F.2d 943, 946 (9th Cir. 1993). Plaintiffs filed timely objections to both of Judge Coffin's findings and recommendations, and defendants timely objected to a portion of Judge Coffin's findings regarding preemption. I give *de novo* review of the parties' objections to the findings and recommendations regarding the motions for relief from judgment, to dismiss, and summary judgment and review for clear error plaintiffs' objection to the denial of their motion for sanctions.

I. Background

The following facts are undisputed. Metoclopramide is a prescription drug that is available in either generic or name-brand formulation. Reglan, the name-brand product, was produced at different times by Wyeth, Schwarz, and Alaven. Pliva and Northstar produce the generic formulation of the medication.

Mrs. Phelps took generic metoclopramide tablets from November 2002 through at least August 2009 as prescribed by her physician. She alleges the metoclopramide caused her to

develop tardive dyskinesia, a debilitating neurological condition characterized by involuntary movements. Plaintiffs allege that the defendants are liable for her injuries because they negligently failed to warn her or her doctors about the risks associated with the long-term use of metoclopramide.

II. Discussion

A. Claims Against Name-Brand Defendants are Dismissed.

Plaintiffs seek relief from judgment with respect to dismissal of their claims against the name-brand defendants on the grounds that *Mensing* overturned the established law. Federal Rule of Civil Procedure 60(b) sets forth the grounds upon which such a motion may be granted. Rule 60(b)(5) permits a party to obtain relief if “the judgment has been satisfied, released or discharged; it is based on an earlier judgment that has been reversed or vacated; or applying it prospectively is no longer equitable.” Fed. R. Civ. P. 60(b)(5). Such motions are infrequently granted. *Twentieth Century-Fox Film Corp. v. Dunnahoo*, 637 F.2d 1338, 1341 (9th Cir. 1980). Here, plaintiffs argue reconsideration of the grant of summary judgment for name-brand defendants is warranted due to the Supreme Court’s decision in *Mensing*. Plaintiffs claim that *Mensing* overturns the law established in *Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994), a case on which Magistrate Judge Coffin relied. In *Foster*, the Fourth Circuit found that the manufacturer of a name-brand prescription drug could not be held liable for an injury caused by the generic version of the drug.

Plaintiffs make two principle objections to Judge Coffin’s findings. First, plaintiffs assert that *Mensing* overturned *Foster*, and thus the court’s reliance on *Foster* is misplaced. Instead, plaintiffs urge the court to follow *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89 (2008) and *Kellogg*

v. *Wyeth*, 762 F.Supp.2d 694 (D. Vt. 2010). Second, plaintiffs argue that their claims are not solely based on product liability, but also sound in negligence and innovator's liability.

The name-brand defendants respond that summary judgment was granted based on the principle of Oregon law that a manufacturer cannot be held liable unless a plaintiff proves that her injuries resulted from the use of that manufacturer's product, and that Mrs. Phelps ingested only generic metoclopramide. Further, defendants claim that there were no federal-law issues relevant to the court's decision to grant their motion for summary judgment. Finally, defendants assert that *Mensing* does not overturn *Foster's* holding concerning the liability of name-brand manufacturers.

Plaintiffs argue that the recent *Mensing* decision overturned the ruling in *Foster*; and consequently, the court improperly relied on *Foster*. In *Foster*, the Fourth Circuit found that name-brand manufacturers could not be held liable for injuries caused by generic formulations of a drug and that a generic manufacturer could add to or strengthen warnings or delete misleading statements on labels. 29 F.3d at 170. In *Mensing*, the Supreme Court held that a generic manufacturer could not change the content of label warnings, even to add additional warnings. 131 S. Ct. at 2575. Thus, while *Mensing* overrules *Foster* with respect to a generic manufacturer's ability to alter labels, it does not overrule *Foster's* holding regarding the liability of name-brand manufacturers. Indeed, the *Foster* court's reluctance to hold name-brand defendants liable for generic drugs did not depend on a generic manufacturer's ability to alter the label, but rather on concepts of foreseeability and duty. Consequently, *Mensing* does not overturn the central holding in *Foster*.

In fact, the Supreme Court acknowledged that the dual holdings of *Foster* and *Mensing*

left the plaintiff there with no remedy, as she could not successfully bring a claim against name-brand manufacturers under *Foster* and was barred on other grounds from suing the generic manufacturers. *Mensing*, 131 S.Ct. at 2581 (acknowledging “the unfortunate hand that federal drug regulation has dealt” plaintiff). The majority further stated that Congress or the FDA could change the law if they wished to provide plaintiffs who had ingested generic medication with a cause of action. *Id.* at 2582. While the outcome is unfortunate, it is evident that *Foster* remains persuasive authority to bar plaintiffs’ claims against name-brand defendants here.

Additionally, plaintiffs argue that *Foster* rests on legally unsound propositions and urge the court to reject its holding. First, plaintiffs argue that *Foster* proposes that it is illogical for a physician to rely on product information provided by a name-brand manufacturer when prescribing a generic. Pl.’s Objections at 14. However, the *Foster* court’s decision rests on its determination of the duty of a name-brand manufacturer, not the proposition that a physician should not rely on information provided by the name-brand manufacturer. Second, plaintiffs argue that name-brand manufacturers owe a general duty of care to patients ingesting generic formulations of the drug and that *Foster* ignored this duty. However, I decline to extend a name-brand manufacturer’s duty so far, as discussed below.

It is undisputed that Mrs. Phelps never ingested metoclopramide manufactured by any of the name-brand defendants. Nor did any of the name-brand defendants supply her with metoclopramide. Under Oregon’s product liability law, the name-brand defendants cannot be found liable for plaintiffs’ injuries because plaintiffs cannot show that their injuries resulted from the use of the name-brand manufacturers’ product. *See McEwen v. Ortho Pharma. Corp.*, 270 Or. 375, 407 (1974). Nonetheless, plaintiffs request that the court apply common law principles of

negligence, fraud, and misrepresentation to extend liability to the name-brand defendants. They argue that regardless of whether Mrs. Phelps ingested the name-brand defendants' product, the name-brand defendants owed her a duty of care.

Plaintiffs assert that a name-brand manufacturer may be held liable for injuries suffered by a patient who takes either the generic or name-brand formulation of a drug, if the injuries were foreseeably caused by negligent or intentional misrepresentations by the pharmaceutical company that induced the purchase and consumption of the drug.

Plaintiffs cite neither Oregon nor federal law to support this proposition. Instead, plaintiffs argue that manufacturers owe a general duty to use care in connection with their conduct to all who may injured by it, if such conduct is carried out in a negligent manner and results in foreseeable injuries. Pl.'s Objections at 6-7 (citing *Palsgraf v. Long Island R.R. Co.*, 162 N.E. 99 (N.Y. 1928)). Plaintiffs assert that, based on federal regulations, name-brand defendants should have known that all generic manufacturers were required to duplicate the information on name-brand labels for generic drugs, and that generic manufacturers were prevented from including additional warnings or independently warning doctors of metoclopramide's risks. Additionally, plaintiffs argue that name-brand defendants knew or should have know that their label did not adequately warn of the risks associated with metoclopramide. Consequently, plaintiffs assert that the generics defendants' reliance on name-brand defendants' labels was a foreseeable cause of their injuries.

I decline to stretch the duty of care for name-brand defendants to cover injuries caused by generic manufacturers' products, given that their argument directly contradicts Oregon law. *McEwen*, 270 Or. at 407 (“(W)e must determine whether each defendant’s negligence could be

found to be a substantial cause of plaintiff's ingestion of the (drug) *manufactured by that defendant.*") (emphasis added). Further, like Judge Coffin, I find the reasoning in *Foster* persuasive. There, the plaintiffs' infant daughter died after being treated with generic Phenergan. *Foster*, 29 F.3d at 167. The plaintiffs brought suit against the name-brand manufacturer for negligent misrepresentation, but the Fourth Circuit ruled that Maryland law did not allow a manufacturer to be liable for an injury caused by a competitor's product. *Id.* at 171. While *Foster* recognized that reliance on the label was foreseeable, the court explained that foreseeability alone does not create a duty of care, and the court specifically rejected the plaintiffs' negligence claim. *Id.* (stating that "we think to impose a duty in the circumstances of this case would be to stretch the concept of foreseeability too far"). The *Foster* court found that there is "(n)o legal precedent for using a name brand manufacturer's statements about its own product as a basis for liability or injuries caused by other manufacturers' products, over whose production the name brand manufacturer had no control." *Id.* at 170. Name-brand defendants cite a plethora of courts which have followed *Foster* and concluded that name-brand defendants cannot be held liable for injuries caused by products produced by a generic manufacturer. *See e.g. Smith v. Wyeth, Inc.*, 657 F.3d 420, 424 (6th Cir. 2011); *Metz v. Wyeth LLC*, ___F.Supp.2d___, 2011 WL 5826005 (M.D. Fl. Nov. 18, 2011). I agree.

Next, plaintiffs encourage the court to reject *Foster* and follow the holdings in *Conte* and *Kellogg*. In both *Conte* and *Kellogg*, the courts analyzed the plaintiffs' labeling misrepresentation claims as negligence claims. The *Conte* court found precedent for extending liability to someone other than the manufacturer, based on a California case extending liability to a company which had endorsed another's product. 85 Cap. Rptr. 299, 311 (Cal. App. 2008). In *Kellogg*, the court

concluded that Vermont's negligence law created a legally cognizable duty for name-brand manufacturers. 762 F.Supp.2d at 706. In contrast, Oregon courts have found that ORS § 30.900 includes all theories a plaintiff may bring in an action based on a product defect. *See Marinelli v. Ford Motor Co.*, 72. Or. App. 268, 273, rev. den., 299 Or. 251 (1985). Consequently, Oregon product liability law is controlling here, and it does not allow for name-brand manufacturer liability unless Mrs. Phelps can demonstrate that the name-brand manufacturers' products caused her injury. *See McEwen*, 270 Or. at 407.

Finally, plaintiffs assert that name-brand defendants are liable as the innovators of metoclopramide. Plaintiffs rely heavily on the reasoning in *Easter v. Aventis Pasteur, Inc.*, 2004 WL 3104610 (E.D. Tex. 2004). In *Easter*, the court held Eli Lilly, the name-brand manufacturer of thimerosal, liable for injuries caused by a generic formulation because Eli Lilly published distorted medical literature and deceived health regulators and physicians as to the safety of the medication. *Id.* at 8. Plaintiffs, however, fail to make such allegations in this case. In 2010, a district court granted summary judgment to name-brand defendants, on claims including innovator liability, in a metoclopramide case on the basis that the plaintiff only ingested the generic manufacturer's products. *Finnicum v. Wyeth, Inc.*, 708 F.Supp.2d 616, 616 (E.D. Tex. 2010). The *Finnicum* court distinguished *Easter* because Lilly designed the vaccine with which the plaintiff was injected. *Id.* at 621. In contrast, the plaintiff in *Finnicum* never ingested a name-brand formulation of metoclopramide nor did the name-brand defendant design the generic formulation. *Id.* Consequently, the court declined to extend liability to name-brand defendants. *Id.* I find the *Finnicum* court's reasoning persuasive.

In sum, while name-brand defendants are required to provide adequate warnings, they

cannot be held liable for injuries caused by a generic manufacturer's products. Plaintiffs' motion for relief from judgment is denied.

B. Plaintiffs' Claims Against Generic Manufacturers are Preempted.

Relying on *Mensing*, Judge Coffin found that federal law preempts state laws that would impose a duty on generic manufacturers to change a drug's label and granted Pliva's motion to dismiss, though Judge Coffin did not dismiss plaintiffs' newly-amended claims. Judge Coffin also denied plaintiffs' motion for partial summary judgment. Plaintiffs object to Judge Coffin's finding of preemption, and defendant Pliva objects to Judge Coffin's denial of the motion to dismiss with respect to plaintiffs' amended failure-to-update claims. Alternatively, Pliva argues the matter should be handled under a new motion for summary judgment.¹

Federal Rule of Civil Procedure 56 allows summary judgment if the pleadings, discovery and disclosure motions on file, and any affidavits demonstrate that there is "no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Put simply, there can be no genuine issue of material fact. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). The movant has the initial burden and must establish that there is no genuine issue of material fact or that a material fact essential for the nonmovant's claim is missing. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-24 (1986). Once the movant has met its burden, the burden shifts to the nonmovant to produce specific evidence that a genuine issue of material fact exists or to establish the existence of all facts material to the claim. *Id.* The

¹Judge Coffin also granted defendant Northstar's motion for summary judgment because Mrs. Phelps ingested only Northstar's product after developing tardive dyskinesia. There are no objections to the recommendation with respect to Northstar; consequently, I adopt Judge Coffin's findings granting summary judgment to Northstar here.

nonmovant needs more evidence than the mere allegations or denials contained in its own pleadings. *See* Fed. R. Civ. P. 56(c)(1).

Additionally, summary judgment is appropriate when federal law preempts a plaintiff's state law claims. *See e.g., Bank of Am. v. City & Cnty. of San Francisco*, 309 F.3d 551, 566 (9th Cir. 2002) (affirming the district court's grant of summary judgment based on federal conflict preemption). Likewise, when federal law preempts all claims in a complaint, dismissal for failure to state a claim is appropriate. *See e.g., Whistler Invs., Inc. v. Depository Trust & Clearing Corp.*, 539 F.3d 1159, 1163 (9th Cir. 2008) (affirming the dismissal of a claim based on federal conflict preemption).

While preemption of all claims warrants summary judgment or dismissal, impossibility preemption is a demanding defense. *Wyeth v. Levine*, 555 U.S. 555, 573 (2009). The party asserting the defense carries the burden of establishing preemption and, in order to prevail, must convince the court that Congress intended to preempt the claims at issue. *Id.*; *Barnes ex. rel. Est. of Barnes v. Koppers, Inc.*, 534 F.3d 357, 363 (5th Cir. 2008) (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). Judge Coffin found that defendants satisfied this burden. Plaintiffs timely filed objections to his findings.

First, plaintiffs again argue that not all of their claims are based in product liability, and therefore, not all of their claims are preempted. Second, plaintiffs assert that *Mensing* did not hold that all warnings-based claims are preempted and that defendants failed to satisfy the demanding standard to demonstrate preemption. Third, plaintiffs state that defendants failed to comply with duties imposed by federal law and that plaintiffs may bring action for those violations.

1. All of plaintiffs' claims are product liability claims.

As they argued with the name-brand defendants, plaintiffs assert that not all of their claims can be distilled down to product liability claims. While Judge Coffin noted that plaintiffs brought a variety of claims, he ruled that all of the claims could be classified as product liability claims, including failure to warn, under Oregon's product liability statute. The product liability statute provides that:

(A) 'product liability civil action' means a civil action brought against a manufacturer, distributor, seller or lessor of a product for damages for personal injury . . . arising out of: (1) Any design, inspection, testing, manufacturing or other defect in a product; (2) Any failure to warn regarding a product; or (3) Any failure to properly instruct in the use of a product.

ORS § 30.900. All of plaintiffs' claims fall under the plain language of this definition.

Regardless of label, all of plaintiffs' claims are premised on defendants failure to warn plaintiffs or Mrs. Phelps's doctors. Consequently, they are properly considered under ORS § 30.900.

Nonetheless, according to plaintiffs, their breach of warranty claims should be considered as both product liability and contract claims. *See Redfield v. Mead, Johnson & Co.*, 512 P.2d 776, 781 (Or. 1973) (finding that the UCC's statute of limitations was applicable when the tort statute of limitations had expired); *Markle v. Muholland's, Inc.*, 509 P.2d 529, 535 (Or. 1973).

However, both cases cited by plaintiffs were decided before ORS §30.900 was passed in 1977.

Since then, Oregon courts have ruled that the statute "embraces *all* theories a plaintiff can adduce in an action based on a product defect," including breaches of warranty. *Marinelli* 72 Or. App. at 273, *rev. den.*, 299 Or. 251 (1985) (emphasis in original); *Kambury v. DaimlerChrysler Corp.*, 185 Or. App. 635, 639 (Or. App. 2003); *Simonsen v. Ford Motor Co.*, 196 Or. App. 460, 466-67 (Or. App. 2004); *Crosswhite v. Jumpking, Inc.*, 411 F.Supp.2d 1229, 1230-31 (D. Or. 2006).

Under the statute, all of plaintiffs' claims are properly considered product liability claims.

2. *Mensing* preempts all warnings based claims against generic manufacturers.

Plaintiffs next argue that *Mensing* does not preempt all of their claims against generic manufacturers. Judge Coffin found that defendants could not comply with the duty to warn plaintiff alleges under Oregon law and the federal labeling rules. Following the analysis in *Mensing*, Judge Coffin found that all of plaintiffs' failure to warn claims, aside from their amended claim alleging a failure to update the label, were preempted.

The Supremacy Clause establishes that federal law is "the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., Art. VI, cl. 2. Consequently, "(w)here state and federal law directly conflict, state law must give way." *Mensing*, 131 S. Ct. at 2570. A conflict of laws exists where it is "impossible for a private party to comply with both state and federal requirements." *Id.* (citing *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)).

Detailed federal statutes and regulations govern labeling requirements for prescription medications. The FDA regulates and approves prescription medication labels. *See* 21 C.F.R. § 314.50 (name-brand labeling); 21 C.F.R. § 314.94(a)(8) (generic labeling). A manufacturer seeking federal approval for a new drug must first prove that it is safe, effective, and that the proposed label is both accurate and adequate. Federal Food, Drug, and Cosmetic Act, codified at 21 U.S.C. § 301 et seq. (FDCA). Generic manufacturers face a less rigorous approval process and can gain FDA approval for generic drug formulations by demonstrating bioequivalence to reference-listed drug that is already approved by the FDA. 21 U.S.C. § 355(j)(2)(A). Additionally, a generic drug application must show that "the labeling proposed for the new drug

is the same as the labeling approved for the listed drug.” 21 U.S.C. § 355(j)(2)(A)(v).² Thus, generic drugs manufacturers “have an ongoing federal duty of ‘sameness’” regarding their warning labels. *Mensing*, 131 S. Ct. at 2575 (accepting FDA’s interpretation that “changes unilaterally made to strengthen a generic drug’s warning label would violate the statutes and regulations requiring a generic drug’s label to match its brand-name counterpart’s”). Under FDA rules, a generic drug manufacturer may not issue additional warnings through Dear Doctor letters nor imply in any way that there is a therapeutic difference between their product and the name-brand formulation. *Id.* at 2576 (adopting the FDA’s argument that Dear Doctor letters qualify as labeling and therefore must be consistent with the approved labeling. 21 C.F.R. § 202.1(I)(2) 21 C.F.R. § 201.100(d)(1)).

Given the broad definition of labeling and the prohibition against generic manufacturers unilaterally altering labels, any state law duty that requires a generic manufacturer to provide additional warnings directly conflicts with federal law. *Mensing* addressed generic manufacturers’ duty to warn, and concluded that failure to warn claims brought under state law were preempted. 131 S. Ct. at 2576.

Plaintiffs encourage an extremely narrow reading of *Mensing*. They assert that *Mensing* did not preempt all state-law failure to warn claims against generic manufacturers; instead,

²Federal regulations define label and labeling broadly. The FDCA defines labeling as “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.” 21 U.S.C. § 321(m). Under the FDA’s regulations “(l)abeling includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce” 21 C.F.R. § 1.3(b). A label is “any display of written, printed, or graphic matter on the immediate container of any article, or any such matter affixed to any consumer commodity or affixed to or appearing upon a package containing any consumer commodity.” *Id.*

plaintiffs argue that the sole issue before the *Mensing* court was whether a generic drug manufacturer could unilaterally change its label to differ from those of the name-brand drug. Here, plaintiffs argue that Oregon law does not require defendant to add warnings to its label, but rather only requires that a generic defendant provide adequate warnings. I fail to understand how defendant Pliva can satisfy Oregon's requirement to provide adequate warnings without changing the label, writing Dear Doctor letters, or otherwise violating the applicable federal regulations. Federal regulations governing generic drug manufacturers directly conflict with, and therefore preempt, state laws that hold generic manufacturers liable for inadequate warning labels on their products. *Mensing*, 131 S. Ct. at 2578.

Relying heavily on *Wyeth v. Levine*, 555 U.S. 555 (2009), plaintiffs also argue that preemption does not apply to their state law product liability claims that are premised on the theory that a different label was necessary to make the drug reasonably safe. However, *Levine* is largely inapplicable here. There, the plaintiff sued the name-brand manufacturer on the basis of its inadequate label. Unlike a generic manufacturer, the name-brand manufacturer could alter the label or otherwise warn the health care community. *Levine*, 555 at 570-71. Here, Pliva, the generic manufacturer, could not alter its label or communicate the necessary information to physicians without violating federal law.

Furthermore, most of the cases decided since *Mensing* have dismissed failure to warn claims brought against generic drug manufacturers on the basis of preemption. For example, in *Smith v. Wyeth, Inc.*, the plaintiffs argued that while *Mensing* altered the theories of liability a plaintiff could pursue, viable causes of action remained against generic drug defendants. 657 F.3d 420, 423 (6th Cir. 2011), *petition for reh'g en banc denied*. The Sixth Circuit disagreed:

[A]s in the present case, the plaintiffs in *Mensing* alleged that their long-term use of generic metoclopramide caused tardive dyskinesia, and they predicated the manufacturers' liability under state law on the failure to provide adequate warnings on the product's label. The Supreme Court held unequivocally, however, that federal law preempts state laws that impose on generic-drug manufacturers the duty to change a drug's label, thus barring the plaintiff's state-law tort claims. The plain language of the *Pliva* decision compels the same result here.

Id. Numerous other courts have acknowledged the preemptive effect of *Mensing*. See e.g., *Del Valle v. Pliva, Inc.*, Case No. B: 11-113 (S.D. Tex. Dec. 21, 2011) (magistrate judge's recommendation that all claims against a generic manufacturer defendants be dismissed with prejudice); *Moretti v. Wyeth, Inc., et. al.*, Case No. 2:08-cv-00396-JCM-CWH (D. Nev. Dec. 6, 2011); *Stevens v. Pliva, Inc.*, No. 6:10-0886 (W.D. La. Dec. 2, 2011); *Gross v. Pfizer, Inc.*, 2011 WL 5865267 (D. Md. Nov. 22, 2011).

Here, plaintiffs assert that Pliva failed to warn Mrs. Phelps, her doctors, and the medical community that long-term use of metoclopramide was likely to cause tardive dyskinesia. However, federal law prevented Pliva from adding additional warnings to its label or sending physicians Dear Doctor letters warning them of the risks. Pliva could not comply with Oregon law and federal law. Consequently, plaintiffs' claims are preempted.

Both the majority and the dissent in *Mensing* recognized the effect the ruling would have on future litigation against generic drug manufacturers. See *Mensing*, 131 S. Ct. at 2581 (“[B]ecause pharmacists, acting in full accord with state law, substituted generic metoclopramide instead, federal law pre-empts these lawsuits We acknowledge the unfortunate hand that federal drug regulation has dealt *Mensing*, *Demahy*, and others similarly situated.”) (Thomas, J.); *id.* at 2592 (“[A] drug consumer’s right to compensation for inadequate warnings now turns on the happenstance of whether her pharmacist filled her prescription with a brand-name drug or a

generic. If a consumer takes a brand-name drug, she can sue the manufacturer for inadequate warnings under our opinion in *Wyeth*. If, however, she takes a generic drug, as occurs 75 percent of the time, she now has no right to sue.”)(Sotomayor, J. dissenting). Nonetheless, the law as it stands preempts plaintiffs claims. Any remedy to which plaintiffs are entitled must come from the legislature and not the courts.

3. Plaintiffs’ other federal law claims fail.

Plaintiffs also bring additional claims against Pliva for misbranding, failure to communicate drug safety information, and failure to test and monitor the effects of metoclopramide. All of the claims are matters of federal, not state, law. When enacting the FDCA, Congress was explicit that only the federal government may bring an action to enforce its provisions. *See* 21 U.S.C. § 337(a) (providing that proceedings for enforcement, or to restrain violations, of FDCA “shall be by and in the name of the United States”). Consequently, failure to comply with the FDCA cannot form the basis for a state-law claim. Plaintiffs cannot sue to enforce the federal statute.

Likewise, plaintiffs’ failure to conduct post-marketing activities and failure-to-test claims cannot be stand-alone causes of action. Rather, they are a part of the failure to warn claim. *See Gross v. Pfizer, Inc.*, 2011 WL 5865267, *4 (D. Md. Nov. 22, 2011) (finding that Pliva’s failure to test and inspect its products “are but a piece of Plaintiff’s larger failure to warn claims”); *Kociemba v. G.D. Searle & Co.*, 707 F. Supp. 1517, 1527 (D. Minn. 1989) (noting that failure to test cannot cause injury and explaining that the claim is subsumed in a design defect or failure-to-warn claim).

Plaintiffs’ reliance on *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011) is

misplaced. *Hughes* involved a medical device and whether the plaintiff's claims were expressly preempted under § 360k of the Medical Device Amendments. The court's holding in *Hughes* does not change the preemption analysis outlined in *Mensing*. Here, plaintiffs' claims are preempted by impossibility; they are not expressly preempted as the claims in *Hughes* were. Moreover, *Hughes* was decided before *Mensing*, and *Mensing* specifically held that a failure to provide information to the FDA or to request assistance in strengthening a name-brand drug's labeling, assuming such a duty existed, did not change its preemption analysis. *Mensing*, 131 S. Ct. at 2577-78. Accordingly, plaintiffs may not proceed on similar claims here.

C. Plaintiffs' Claim Based on Pliva's Failure to Update the Label Will Not be Considered at this Stage of the Proceedings.

On November 22, 2011, plaintiffs filed their first amended complaint. They brought a negligence per se claim based on Pliva's failure to update its label to contain the new warnings added by the name-brand manufacturer in violation of federal regulations. Magistrate Judge Coffin denied Pliva's motion to dismiss with respect to the new claim. Similarly, Judge Coffin denied without prejudice plaintiffs' motion for summary judgment on the basis that defendants had not had an adequate chance to respond to the amended complaint.

Pliva argues that the failure to update claims are preempted under *Mensing* in their limited objections to the findings and recommendations. In contrast, plaintiffs argue that their motion for summary judgment should have been granted on their negligence per se claim. The issue is not properly before this court, as Pliva has filed a new motion for judgment on the pleadings. This court will not consider the merits of the new allegations until Judge Coffin has fully reviewed them.

D. Plaintiff's Motion for Sanctions is Denied.

Plaintiffs object to Judge Coffin's denial of their motion for sanctions against Pliva, based on Pliva's alleged failure to make required disclosures and to cooperate during discovery. A magistrate judge may hear and rule on certain pre-trial matters, including a motion for sanctions pursuant to 28 U.S.C. § 636(b)(1)(A). A district judge may reconsider a magistrate's order where it is clearly erroneous or contrary to law. *Id.*; Fed. R. Civ. Pro. 72(a); *Henry v. Gill Indust., Inc.*, 983 F.2d 943, 946 (9th Cir. 1993) (stating that the "court's discretion will not be disturbed unless we have a definite and firm conviction that the court committed a clear error of judgment . . ."). I find no clear error in Judge Coffin's ruling.

Counsel is involved in multiple metoclopramide cases. While this case was stayed in January of 2011 pending the Supreme Court's decision in *Mensing*, counsel was actively litigating other metoclopramide cases. While reviewing discovery in another case in February of 2011, plaintiffs' counsel, Mr. Donahue, discovered copies of Pliva's metoclopramide product label that were requested but never produced in this litigation. The labels purportedly showed that Pliva failed to update its labeling in 2003 and 2004 to include changes made to the brand-name metoclopramide label. After making the discovery, Mr. Donahue contacted Pliva's counsel, Mr. Littrell, concerning the label discrepancies. On March 11, 2011, Mr. Littrell responded by sending a letter to "Metoclopramide Plaintiffs' counsel" (including Mr. Donahue) and to the Clerk of the United States Supreme Court informing counsel that Pliva's metoclopramide label had differed from the name-brand drug's label for over five years. The letter included production of Pliva package inserts.

Plaintiffs argue that Pliva violated Rule 26 by failing to produce copies of its

metoclopramide labels for the time period between 2003 and 2008. Furthermore, plaintiffs assert that the failure to produce the labels severely prejudiced plaintiffs and request the striking of Pliva's preemption defense as a sanction. Judge Coffin properly denied plaintiffs' motion.

As Judge Coffin noted, Rule 26 requires the court to sanction an attorney or party who improperly certifies that disclosures are correct, complete and consistent with these rules. Fed. R. Civ. P. 26(g)(1) and (3). The record indicates that Pliva's counsel responded to plaintiffs' request for labeling and packaging inserts by stating that it would produce this evidence after a protective order was entered. Such a response does not indicate that the requested production was complete and plaintiffs did not object to the response. Neither Mr. Littrell nor Pliva improperly certified the discovery response. Consequently, Judge Coffin's finding is not erroneous or contrary to law.

Similarly, Judge Coffin did not error when denying sanctions under Rule 37(b). Rule 37(b) primarily permits sanctions for the failure of a witness to attend a deposition or failure of a party to make a witness available. Fed. R. Civ. P. 37(b). To prevail on a motion for sanctions under Rule 37(b), the movant must show that the nonmovant violated a discovery order and acted in bad faith. *Id.*; see *Lee v. Walters*, 172 F.R.D. 421, 425 (D. Or. 1997). Pliva did not violate a discovery order and Judge Coffin found that there was no indication of bad faith in the record.

While Rule 37(d) does not require the violation of a discovery order or bad faith, it mandates that a motion for sanctions include certification that the "movant has in good faith conferred or attempted to confer with the party failing to act in an effort to obtain the response without court action." Fed. R. Civ. P. 37(d)(B). Following the issuance of the protective order, plaintiffs did not renew their request or contact Pliva regarding the labeling evidence until plaintiffs' counsel located the evidence in another case. There was no attempt to confer with

Pliva. Once Pliva was informed of the labeling discovery, Pliva promptly sent a letter including the relevant package inserts to plaintiffs' counsel. Finally, Pliva's failure to produce the labeling evidence before discovery closed did not prejudice plaintiffs. After the discrepancies were discovered, plaintiffs were allowed to amend their complaint to include claims for failure to update. Thus, plaintiffs' motion for sanctions was properly denied.

III. Conclusion

For the reasons explained above the Findings and Recommendations issued on November 23, 2011 and November 30, 2011 (docs. # 256 & 260) are ADOPTED. Plaintiffs' motion for relief from judgment (doc. # 233) is DENIED, defendant Northstar's motion for summary judgment (doc. # 190) is GRANTED, and Pliva's motion to dismiss (doc. # 188) is DENIED with respect to the failure to update claims and GRANTED in all other respects. Plaintiffs motion for partial summary judgment (doc. # 192) is DENIED. Plaintiffs motion for sanctions against Pliva (doc. # 271) is DENIED. Pliva's motion to strike plaintiffs' motion for sanctions (doc. # 279) is DENIED, and Pliva's motion to strike plaintiffs' notice of supplemental authority (doc. # 287) is DENIED. While this outcome may place plaintiffs in an unfortunate position, as they cannot recover for injuries allegedly caused by the ingestion of generic metoclopramide from either name-brand or generic defendants, it is a result compelled by law.

IT IS SO ORDERED.

Dated this 24 day of April, 2012.



Ann Aiken
Chief United States District Judge